Basic data

Name of the Researcher: Dr. Shweta Mayur Chaudhary

Name of the Guide: Dr. Preetam Shah

Institute where Research will be carried out: Bharati Vidyapeeth Deemed to be University Dental College and Hospital

Title of Research: "Development of Artificial Intelligence (AI) based predictive model for dental caries detection in the pediatric population through intra oral pictures and a comparative evaluation of its diagnostic accuracy in detecting dental caries with clinical assessment: a cross sectional diagnostic accuracy study."

Research Related Information

1. **Overview of Research**

a. Back ground information/ Need for Research

The current trend of paperless, cashless, telemedicine, teleconferencing, satellite technology, many other automations is made possible by advances in material science and technology. [1]

Early Childhood Caries (ECC) is the most common childhood disease worldwide and a health disparity among underserved children. ECC is preventable and reversible if detected early. However, many children encounter barriers to dental care due to ignorance or sometimes negligence. An at-home caries detection technology could potentially improve access to dental care reaching out across all socio economic strata. With increasing digitalization, at home methods of detection could assist in a substantial rise in parents/ guardians seeking treatment for their children. [6]

Also, emphasizing the Dental Home Concept proposed by the American Academy of Pediatric Dentistry (AAPD) with its reiteration in the Reference Manual of the American Academy of Pediatric Dentistry 2022, 21:2, which is the ongoing relationship between the dentist and the patient, inclusive of all aspects of oral health care delivered in a comprehensive and continuously accessible way.

It is the need of the hour to develop artificial intelligence (AI) in such a way that AI powered technology would be used as a diagnostic test (index test) to detect dental caries and provide a caries risk assessment using children's photographs.

b. Aims and Objectives

Research Aim: To develop an Artificial Intelligence (AI) based predictive model for detection of dental caries in the pediatric population through intra oral pictures and a comparative evaluation of its diagnostic accuracy in detecting dental caries with clinical assessment.

Research Objectives:

1. To develop an Artificial Intelligence (AI) based predictive model to detect dental decay in the pediatric population from children's oral photographs.
2. To assess the diagnostic accuracy of the Artificial Intelligence (AI) based predictive model using G. V. Black's caries classification as the reference standard.
3. To assess the diagnostic accuracy of the Artificial Intelligence (AI) based predictive model using ICDAS as the reference standard.
4. To compare the accuracy of AI with clinical caries assessment using G. V. Black's caries classification as the reference standard
5. To compare the accuracy of AI with clinical caries assessment using ICDAS as the reference standard

Study Hypotheses:

A joint hypothesis is proposed for this diagnostic accuracy study, with one component about the test's sensitivity and a second about its specificity.

	Reference standard positive	Reference standard negative
Index test positive	True positive (tp)	False positive (fp)
Index test negative	False negative (fn)	True negative (tn)

Accuracy measures:

- Sensitivity: tp/ (tp+fn)
- Specificity: tn / (tn+fp)
- Positive predictive value: tp / (tp+fp)
- Negative predictive value: tn / (fn+tn)
- Diagnostic odds ratio: (tpXtn) / (fnXfp)
  Output of a diagnostic accuracy study: the contingency (2X2) table

2. Study design

4.1Source of Data

Intra oral images will be taken from patients visiting the Department of Pedodontics and Preventive Dentistry, Bharati Vidyapeeth Deemed to be University Dental College and Hospital. The data collection will be cross sectional with no interventions.

4.2 Inclusion and Exclusion criteria of study participants

Inclusion criteria:

- Children will be selected according to the age criterion (1-14yrs)
- Patients with Frankl's ratings positive and definitely positive
- Consenting parents having access to a smartphone

Exclusion criteria:

- Children with developmental defects on the teeth
- Children with any systemic diseases
- Children wearing any intraoral appliances

4.3 Study Groups

This study will be performed in two Phases:

Phase 1:

Patients visiting the Department of Pedodontics and Preventive Dentistry will be selected by convenience sampling once they clear the inclusion and exclusion criteria, The participants would form a consecutive series. 30 intraoral images in each category will be taken by the primary investigator for development of the artificial Intelligence, a total of 1020 images.

Phase 2:

Post development, clinical correlation will be done using intraoral images obtained from 2211 patients and teeth will be categorised according to caries location as Classes I to VI and according to the extent as 0-6. These patients would also form a consecutive series.

Caries risk assessment will be done according to the American Dental Association (ADA) caries risk assessment form (2009, 2011) for ages 0-6yrs and >6yrs and patients will be categorised as mild, moderate and severe risk patients.

4.4 Materials and Methods with Method of Data Collection including sampling size and sampling procedure and method of data analysis.

Phase 1:

Photographic images:

Intra oral images (30 per category) will be taken for

1. Type of tooth: Incisor, Canine, Premolar, Deciduous Molar, Permanent Molar.
2. Dental decay and decay free images from occlusal, labial (front), buccal (right, left) aspects categorized by location of decay
3. Extent of carious lesion (0-6)

Images will be studied and integrated into the artificial intelligence system. So, a total of 4 maxillary and 4 mandibular images would be taken for each oral cavity:

Upper front

Upper right (Patient's right)

Upper left (Patient's left)

Upper occlusal or chewing surface of teeth

Lower front

Lower right (Patient's right)

Lower left (Patient's left)

Lower occlusal or chewing surface of teeth

A total of 1020 images will be taken.

Specifications for image taking:

All the images will be photographed with a single Smartphone (Samsung Galaxy A23 5G, Model name SM-A236E/DS Android version 13, 50MP main camera) and RingFlash after tooth cleaning

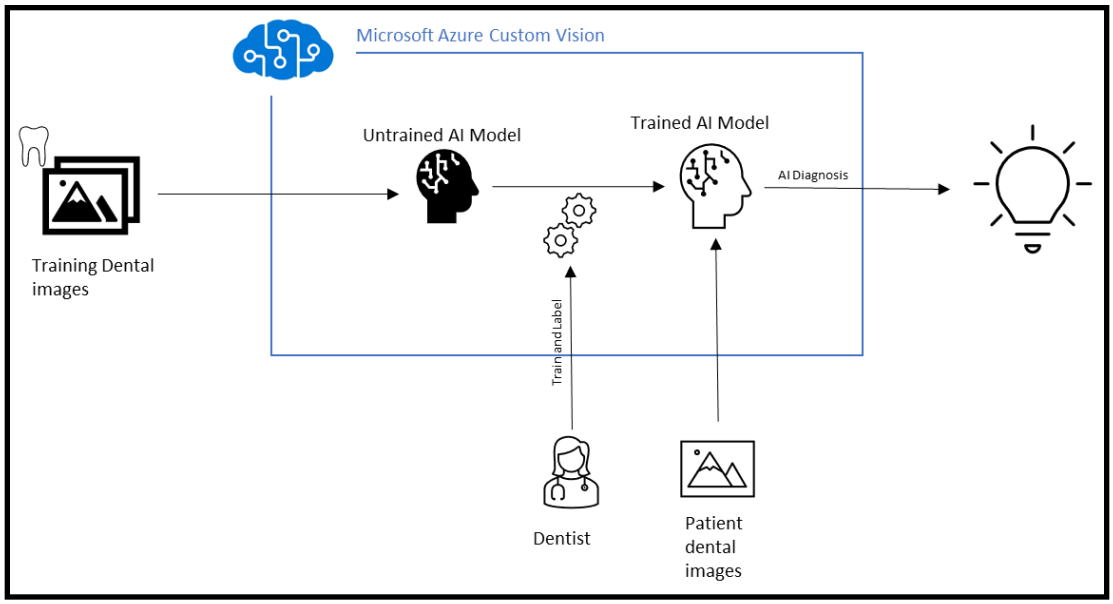
and drying. Molar teeth will be photographed indirectly using intraoral mirrors warmed before positioning in the oral cavity to prevent condensation on the mirror surface. For all photographs, distance between the smartphone and the teeth will be at least 24cm upto 32cm with the lens in the same horizontal plane as the teeth. To ensure the best possible image quality, inadequate photographs (e.g., out-of-focus images or images with saliva contamination) will be excluded. Furthermore, duplicated photos from identical teeth or surfaces will be removed from the data set. With this selection step, it will be ensured that similar clinical photographs will be included once only. All jpeg images (RGB format, resolution 1,200 × 1,200 pixel, no compression) will be cropped to an aspect ratio of 1:1 and/or rotated in a standard manner using image editing software (Microsoft photo editor) until, finally, the tooth surface would fill most of the frame. With respect to the study aim, only images of healthy teeth or carious surfaces will be included. Photographs with (additional) noncarious hard tissue defects (e.g., enamel hypomineralization, hypoplasia, erosion or tooth wear, fissure sealants, and direct and indirect restorations) were excluded to rule out potential evaluation bias. Finally, 1020 anonymized, high quality clinical photographs will be included.

The images obtained will be categorised by the location of the caries according to **G. V. Black's classification of caries (1908)** as Class I to Class VI and according to **The International Caries Detection and Assessment System (ICDAS) (2002)** as extent of decay 0-6.

The data obtained will be integrated into the artificial intelligence system.

Microsoft Azure cloud-based technologies will be used to reduce complexity and increase efficiency.

Microsoft Azure Custom Vision will be used to train AI Model to recognize teeth (Incisor, canine, premolar and molar). Azure Custom Vision is an image recognition service that allows building, deploying and improving upon previous image identifier models.



Phase 2:

Diagnostic Instruments: Mouth Mirror, WHO Probe, a pair of tweezers, cotton pellets, air water syringe

Children from the age of 1 to 14 years will be selected according to the inclusion criteria from the patients visiting the Pedodontics and Preventive Dentistry Department of Bharati Vidyapeeth Deemed to be University Dental College and Hospital. The participants would form a consecutive series.

After development of the artificial intelligence, clinical evaluation of the same will be done. Parents of patients consenting to participate in the study will be shown a short explanatory video guiding them in the process of taking optimal intraoral images for their children/ wards. The child will be required to perform toothbrushing before intraoral images are clicked. The children as well as their images will be coded. 2211 patients will be employed for the study after evaluation of the images on the basis of resolution (minimum 5 MP) and blurring and categorised as acceptable or nonacceptable. The nonacceptable ones will be rejected and patient asked to retake the image. 8 images per patient will be taken with a total of 2211 X 8 = 17,688. Intraoral photography will serve as the diagnostic test.

The acceptable images will be further evaluated as carious or non carious. Sensitivity will be kept at 91% and specificity will be kept at 93% at a precision level of 0.03.

The carious ones will be further categorised by the location of the caries according to **G. V. Black's classification of caries (1908)** as:

Class I: Caries affecting pits and fissures on occlusal third of molars and premolars, occlusal two-thirds of molars and premolars, and lingual part of anterior teeth.

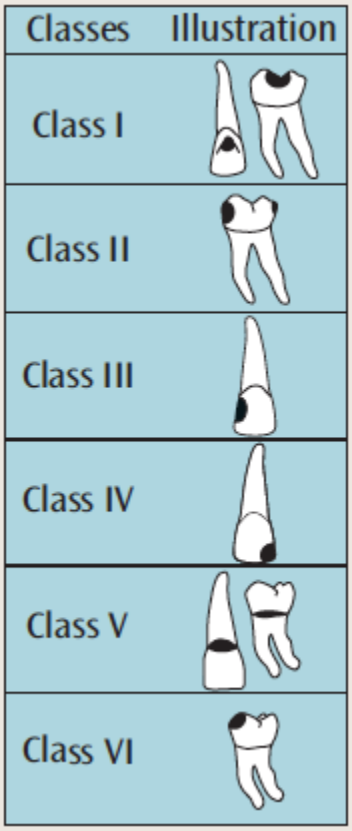
Class II: Caries affecting proximal surfaces of molars and premolars.

Class III: Caries affecting proximal surfaces of central incisors, lateral incisors, and cuspids without involving the incisal angles.

Class IV: Caries affecting proximal including incisal angles of anterior teeth.

Class V: Caries affecting gingival one-third of facial or lingual surfaces of anterior or posterior teeth.

Class VI: Caries affecting cusp tips of molars, premolars, and cuspids



This image will be employed in evaluating the extent of the carious lesions. According to **The International Caries Detection and Assessment System (ICDAS)(2002)**the carious lesions will be classified as under:

0	Clinically sound
1 to 2	Clinically detected “intact” enamel lesions (initial stage decay) (Image a)
3 to 4	Clinically detectable early, shallow, or microcavitations (moderate decay) (Image b, c)
5 to 6	Clinically detectable late or deep cavitations (extensive decay) (Image d, e, f)

G. V. Black's classification and ICDAS will serve as the reference standard.

Rationale for choosing the reference standard:

G. V. Black's classification for caries came into existence in the early 1900s. It is one of the easiest ways to describe carious lesions based on the anatomical location on the tooth.

The ICDAS came into existence in 2002 by a group of cardiologists and epidemiologists for caries diagnosis which was proposed as a way to put forward a globally accepted caries detection system. The index was based on visual examination with the help of WHO probe. The ICDAS classifies the caries process into five stages, ranging from first visible signs of dental caries in enamel to excessive cavity with visible dentin that replicate different phases in the occurrence of dental caries on tooth surfaces and the different levels of treatment, ranging from preventive to operative care. The aim of ICDAS is to present a flexible, yet reliable, system in caries estimation so that clinicians and researchers have the choice based on the phase of caries process and other features according to the requirements of their research or practice. Validity and reproducibility of ICDAS have been field tested. This test overcomes some of the limitations of the more traditional DMF Index like lack of differentiation between filled and carious tooth and difficulty in determining the cause of a missing tooth.

The results of AI will be clinically correlated by a visual - tactile inspection using investigator blinding.Participants would be coded and hence the primary investigator would be blind to the clinical information and reference standard results. Nor will the primary investigator have access to the index test results till clinical evaluation is being done.

Caries risk assessment will be done according to the American Dental Association (ADA) caries risk assessment form (2009, 2011) for ages 0-6yrs and >6yrs and children categorised as low risk, moderate risk and high risk.

	Reference Standard Positive	Reference Standard Negative	Total
Index test positive	a (true positives)	b (false positives)	(a+b) test positives
Index test negative	c (false negatives)	d (true negatives)	(c+d) test negatives
Total	(a+c) disease positives	(b+d) disease negatives	(a+b+c+d) study total

For this study, the external validity seems to hold good owing to the

i. very widespread usage of smart phones by adults

ii. routine image clicking of children by parents/ guardians ensuring optimum cooperation

iii. Image clicking done in the comfort of their homes

SAMPLE SIZE ESTIMATION

Input Data

Type I error (alpha, significance)	0.05
Type II error (Beta, 1-power)	0.20
Proportion (Sensitivity)	96.3%
Expected Sensitivity	0.91
Expected Specificity	0.93
Expected Prevalence	0.37
Desired Precision	0.03
Confidence level	95%

TOTAL SAMPLE SIZE

SAMPLE SIZE CALCULATION BASED ON SENSITIVITY OR SPECIFICITY:

$TP+FN = Z^2 \times Sensitivity\ (1-Sensitivity)/W^2$

$TN + FP = Z^2 \times Specificity\ (1 - Specificity)/ W^2$

Z = 1.96 (Normal distribution)

FORMULA

$$n = \frac{Z^2 * P(1-P)}{\Delta^2} \qquad (1)$$

n will be $(a+c)$ if we use Sensitivity as P, and n will be $(b+d)$ if we use Specificity as P in formula (1).

$$N = \frac{(a+c)}{\text{Prevalence}} \qquad (2)$$

$$N = \frac{(b+d)}{(1-\text{Prevalence})} \qquad (3)$$

We will use the sample size calculation methods of Buderer et al.1996.[1] In this method, we need first to calculate the TP+FN for sensitivity and the TN+FP for specificity through the following equation.

	Precision	**Sample size**
Sample size for sensitivity	0.02	2211
Sample size for specificity	0.02	994

Hence the total sample size: 2211

Reference: Bernard Rosner. Fundamentals of Biostatistics (5th edition). (Based on equation 8.27)
Reference study for sample size estimation: Kühnisch I J , Meyer O, Hesenius M, Hickel R, and Gruhn V. Caries Detection on Intraoral Images Using Artificial. Journal of Dental Research 2022;101(2):158–165

Software used: Diagnostic test calculator Alan Schwartz
http://araw.mede.uic.edu
https://www.medcalc.org/manual/sample-size-calculations.php

Type of Study (please tick)

Basic Sciences	☐	Clinical	☐	Cross sectional ✔	☐
Retrospective	☐	Epidemiological/Public Health ✔	☐	Case Control	☐
Prospective	☐	Socio-behavioural	☐	Cohort	☐
Qualitative Review	☐	Biological Samples/Data	☐	Systematic	☐
Mixed Method	☐	Any other(specify)	☐		

4.5 Outcome Measures

The results of AI will be clinically correlated by a visual - tactile inspection using investigator blinding.

Caries risk assessment will be done according to the American Dental Association (ADA) caries risk assessment form (2009, 2011) for ages 0-6yrs and >6yrs and children categorised as low risk, moderate risk and high risk.

4.6 Applicable only for clinical trials

NA

3. Assessment of efficacy

5.1 Specification of the efficacy parameters

Tooth categorisation will be done as under:

1. Type of tooth: Incisor, Canine, Premolar, Deciduous Molar, Permanent Molar.

2. Dental decay and decay free images from occlusal, labial (front), buccal (right, left) aspects using G V Black's classification for location of caries

3. Extent of lesion (0-6)

5.2 Methods and timing for assessing, recording, and analyzing of efficacy parameters

The results of AI will be clinically correlated by a visual - tactile inspection using investigator blinding.

Caries risk assessment will be doneaccording to the American Dental Association (ADA) caries risk assessment form (2009, 2011) for ages 0-6yrs and >6yrs and children categorised as low risk, moderate risk and high risk.

4. Details of Statistical Analysis

The statistical analysis will be done using Statistical Package for Social Sciences (IBMSPSS Statistic for window,version 21.0.Armonk,NY:IBMCorp.)

The analysis will be done using relevant statistical tests at 95% confidence interval and 80% power to the study. Statistical significance was kept at $p<0.05$.

Accuracy, sensitivity and specificity of the artificial intelligence will be evaluated as follows:

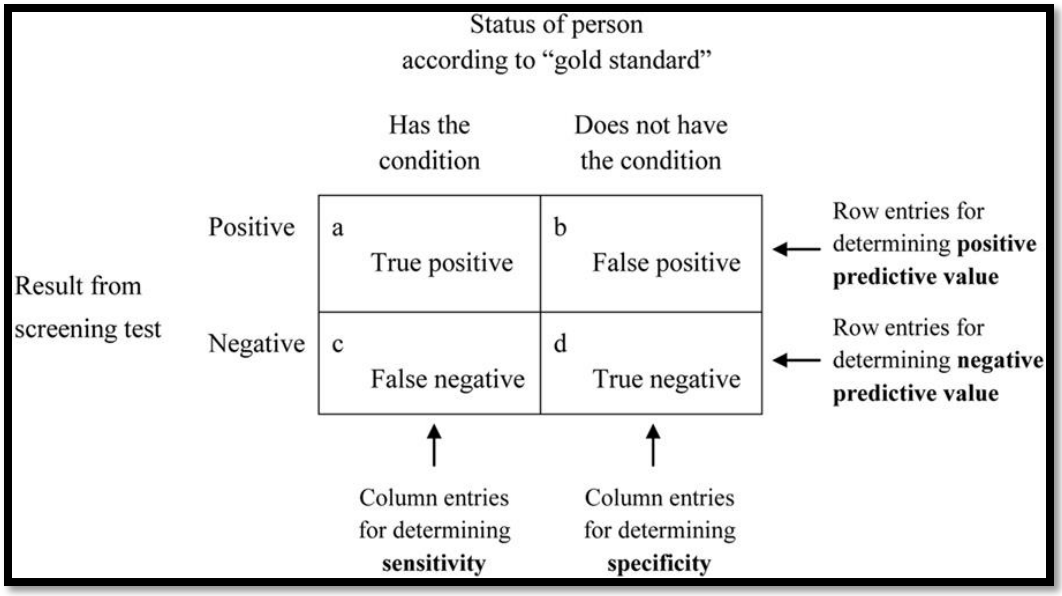
Accuracy = (sensitivity) (prevalence n) + (specificity) (1 - prevalence).

Sensitivity=$[a/(a+c)]\times100$

Specificity=$[d/(b+d)]\times100$

Positivepredictive value(PPV)=$[a/(a+b)]\times100$

Negative predictive value(NPV)=$[d/(c+d)]\times100$.



Minimally acceptable criteria for Diagnostic accuracy

Identifying the existing clinical pathway in which the index test will be used (will be used in existing carious teeth in children aged 1-14yrs)

⬇

Define the role of the index test in the clinical pathway (to identify and classify dental caries)

⬇

Define the expected proportion of patients with the target condition(prevalence of caries52% among 3–18 years of age (*P* < 0.0001))

⬇

Identify the downstream consequences of test results (participants will experience easily accessible detection of dental caries and motivation to visit a dental professional for treatment)

⬇

Weigh the consequences of test misclassifications (there could be a delay in seeking treatment)

⬇

Define the study hypothesis by setting minimally acceptable criteria (MAC) for sensitivity and specificity(80 sensitivity and 80 specificity)

⬇

Perform a sample size calculation (explained above)

⬇

Arrive at meaningful conclusions

Section C – Participant Related Information

5. **Recruitment of Research Participants**

a. Type of participants in the study

Healthy volunteers ☐ Patients ✔ ☐ Vulnerable persons/Special groups ✔ ☐

Others (specify) ☐

b. Who will do the recruitment : Principal Investigator

c. Participant recruitment methods used :

Posters/leaflets/letters ☐

TV/Radio Ads/Social Media/Institution Website ☐

Patients/Family/Friends visiting hospitals ✔ ☐

Telephone ☐

Others ☐

d. Will there be vulnerable persons/special groups involved?

Yes ☑ No ☐ NA ☐

ii. If yes, type of vulnerable persons/special groups

Children under 18 yrs ☑ Pregnant or lactating women ☐

Differently abled (Mental/Physical) ☐ Employees/Students/Nurses/Staff ☐

Elderly ☐ Institutionalized ☐ Economically and socially disadvantaged ☐

Refugees/Migrants/Homeless ☐ Terminally ill (stigmatized or rare diseases) ☐

Any other (Specify): …..☐…

6. Assessment of safety of trial subjects/research participants

8.1 Specification of safety parameters.

As this is a noninterventional observational study, no specific safety parameters are involved. Patients lacking cooperation will not be included in the study.

8.2 The methods and timing for assessing, recording, and analyzing safety parameters.

NA

8.3 Procedures for eliciting report of and for recording and reporting adverse event

Since this is a noninvasive study involving clicking of photographs in cooperative children, involving only the use of diagnostic instruments intraorally, likelihood of any adverse event is less than minimal. Inadverdent soft tissue injury due to the instruments could occur rarely.

In case of an adverse event, it will be reported as per the Department Protocol including written documentation of the date and time of the adverse event, its management, precautions to be taken henceforth for its prevention and the signature of the supervising staff.

8.4 The type and duration of the follow-up of subjects after adverse events, if any.

Any management or treatment to be provided will be done at Bharati Vidyapeeth Medical/ Dental College free of cost for the patient.

8.5 Is there any reimbursement to the participants? No

If yes, Monetary ☐ Non-monetary ☐ Provide details ……

8.6 Are there any incentives to the participants? No

If yes, Monetary ☐ Non-monetary ☐ Provide details …… ……

8.7 Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution? No

If yes, Monetary ☐ Non-monetary ☐ Provide details ……..……
……

9 Risk and Benefits

9.1 What are the potential risks to the subjects? (Consider social and emotional risks as well as more obvious physical risks)

Less than Minimal risk ☑ Minimal risk ☐

Minor increase over minimal risk or low risk ☐

More than minimal risk or high risk ☐

If Yes, Describe the risk management strategy…….

9.2 What are the potential benefits from the study ?

For the participant ✔ ☐

For the society/community ✔ ☐

For improvement in science ✔ ☐

Please describe how the benefits justify the risks:Development of artificial intelligence will be beneficial to the society at large by reducing the workload on an already overburdened medical infrastucture.

9.3 Are adverse events expected in the study?

Since this is a noninvasive study involving clicking of photographs in cooperative children, involving only the use of diagnostic instruments intraorally, likelihood of any adverse event is less than minimal. Inadverdent soft tissue injury due to the instruments could occur rarely.

Are reporting procedures and management strategies described in the study?

Yes

9.4 What are the compensations for unexpected risks?

The treatment for the same will be done free of cost at Bharati Vidyapeeth Medical/ Dental Hospital

9.5 What are the potential benefits to the participating subjects?

They would become aware of their caries risk status and hence be internally motivated to seek dental treatment.

10 Safety and other controls

Does this study involve ionizing radiation, hazardous substances, or hazardous or invasive procedures (including radiological imaging, venepuncture or intimate physical examination)?

NO

11 Informed Consent:

11.1 Waiver of consent

Are you seeking waiver of consent?

No

11.2Are you seeking waiver of consent?

If no, answer below

Provide a copy of your consent form and information sheet. Write the procedureabout the following:

a. How will consent be obtained from subjects? Will there be a written explanation of the study? How will risks and benefits be explained? It will be a written informed consent in the patient's choice of language.

b. Type of consent planned for:

Signed consent ☑ Verbal/Oral consent Witnessed ☐ nsent ☐

Consent from Legally Authorized Representative (If so, specify from whom) : ☐

Audio-Video (AV) consent ☐

Verbal assent from minor (7-12 yrs) along with parental consent ✔ ☐

Other ☐ (specify)
.....

c. Who will obtain the informed consent?
PI/Co-I ☑ Nurse/Counselor Research staff ☐

Other (Specify) …….....……...

d. Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ✔ Local language ✔ Other ☐ ☐
(Specify) - Hindi, and Marathi

e. Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language ✔ Risks and discomforts ✔ ☐

Alternatives to participation ✔ Right to withdraw ✔ ☐

Benefits ✔ Purpose and procedure ✔ ☐

Data/ Sample sharing ✔ Need to recontact ✔ ☐

Confidentiality Storage of samples ✔ ☐

Return of research results ✔ Payment for participation ✔ ☐

Compensation for study related injury ☑ Statement that consent is voluntary ✔ ☐

Commercialization/ Benefit sharing ✔ Statement that study involves research ✔ ☐

Use of photographs/ Identifying data ✔ ☐

Contact information of PI and Member Secretary of EC ✔ ☐

Others ☐
(Specify)…….

f. What data will be collected on those who refuse consent?
(Such participants will not be included in the study)

12. Confidentiality

Method of maintaining confidentiality of participants (Explain how the confidentiality will be maintained)

All participants will be coded numerically.

13. a) Consent of the participant/ subject (copies attached in 3 different languages)
b) Patient / information sheet (copies attached in 3 different languages)
c) Student undertaking (only in English)
d) Waiver of consent (if applicable)(only in English) - not applicable

14. Agreement between collaborating partners
(if applicable- mention details with documentary evidence)
Not applicable

15. I agree and undertake to do the following
To report serious adverse events to the IEC
To report conflict of interest, if any

Dr. Shweta Chaudhary
Principal Investigator: Name and Sign

Dr. Preetam Shah
P.G. Guide:Name and Sign

Dr. Alok Patel
Head of department: Name and Sign Seal of the Department

Collaborator
Designation & Organization (if applicable):

Chairperson, Institutional Ethics Committee: Member Secretary, InstitutionalEthics Committee:

Undertaking by the Investigator

01. This research project (including collection of blood or tissues samples for research) will not be started until the final approval of the BVDUDC&H-PUNE-IEC has been obtained.
02. We agree to undertake research proposal involving human subjects and follow the protocol as per the **ethical principles of Declaration of Helsinki.Good Clinical Practice Guidelines and Ethical Guidelines for Biomedical Research on Human Subjects, issued by Indian Council of Medical Research and National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017**. We will not modify the research protocol, consent, etc. without prior approval by the BVDUDC&H-PUNE-IEC.
03. The investigators agree to obtain a properly informed and understood consent for all research subjects before their inclusion in the study in the informed consent form that is approved by the BVDUDC&H-PUNE-IEC. Participants will receive an 'information sheet' which will detail the project design in simple understandable layperson's language.
04. The investigators agree to report within a week all serious adverse events (SAE) associated with the study in the SAE form to the BVDUDC&H-PUNE-IEC. In the event of a death of the study subject, the Secretary, BVDUDC&H-PUNE-IEC and SRC, will be informed within 24 hours.
05. The investigators agree to submit annual progress report of the study in the appropriate form. A final report will be submitted at the end of the study.
06. Full details on funding and a proposed budget are included with the study proposal. The proposed budget is presented on the specific budget sheet

07. We understand that the BVDUDC&H-PUNE-IEC is concerned about transparent financial transactions during the study. A report on how the study funds were utilized will be presented to the EC along with the final project report at the end of the study.(**In case of sponsored study**)

08. For all research proposals that are sponsored by a pharmaceutical or biomedical company, we the investigators will ensure that the Sponsor Company will underwrite all expenses such that neither the hospital nor the study participants are made to spend while participating in the study. The investigators will also ensure that in the event of complications arising directly due to the study or litigation, the cost of management or legal fees will be borne by the Sponsor Company totally.

09. The investigators state that they do not stand to gain financially from the commercial sponsor and don't have conflict of interest in the drug or product by way of consultations, shareholding, etc.

10. The investigators will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the BVDUDC&H-PUNE-IEC, approved protocol.

11. All data collected during the research project, including those supported by commercial sponsors (e.g. pharmaceutical company), will remain the property of BVDUDC&H-PUNE.

12. The salaries to staff employed for the research project will be as shown in the budget sheet and in accordance with the provisions made by the funding agencies. .(**In case of sponsored study**)

13. The case records (source documents) will be made available to members of the SRC or BVDUDC&H-PUNE-IEC any time for random verification and monitoring. The case records (source documents) will be preserved in the premises of BVDUDC&H-PUNE for at least 5 years after the last approval of application or publication.

14. The investigators promise to ensure that there is no falsification of data when compared to the source documents. We agree to clarify any doubts or discrepancies that may arise during the data monitoring evaluation.

15. All the findings and conclusions of the proposed project such as review of case records, analysis of forms of treatment, investigations, etc will be first presented to the staff members of BVDUDC&H-PUNE before they are released or presented elsewhere. The investigators will submit a copy of the abstract to the SRC and BVDUDC&H-PUNE-IEC well in advance of any proposed presentation at national or international conferences or seminars.

16. The investigators will not issue any press release before the data and conclusions have been peer-reviewed by the BVDUDC&H-PUNE staff or published in a peer-reviewed journal.

17. All serious injuries arising from the study will be the responsibility of the investigators. The investigators agree to ensure that the sponsors undertake a product liability insurance to cover any expenses for injury or compensation arising from the study treatment.

18. The investigators agree to transfer 15% of the total budget to BVDUDC&H-PUNE as service charges. This will not apply to intramural projects, those co-sponsored by BVDU Dental College & Hospital Pune and collaborative projects with BVDUDC&H-PUNE
19. The investigators agree that the grant money will be spent in accordance with the budget proposal only. The funds will not be used for any other purposes without prior approval from the BVDUDC&H-PUNE-IEC. Thirty percent of the surplus grant if left over at the end of the study will be credited to BVDUDC&H-PUNE The remaining 70% of the surplus grant money may be used by the investigators for conducting intramural research, improving teaching facilities in the department, providing financial assistance to investigators for conferences, etc after obtaining permission from the BVDUDC&H-PUNE-IEC. In case of government grants, the unspent balance will be spent/ returned as per the directives given along with the project sanction letter.
20. The investigators will constantly inform the BVDUDC&H-PUNE-IEC about amendments in the study protocol, data collection forms, informed consent forms, budget expenses, salaries, other study documents, etc. as and when they occur. No major changes in the treatment arms or the study protocol or randomization technique will be carried out without prior permission of the BVDUDC&H-PUNE-IEC.
21. The investigators will comply with all policies and guidelines of the BVDUDC&H-PUNE and affiliating/collaborating institutions where this study will be conducted, as well as with all applicable laws regarding the research.

We the investigators of the proposed study have read all the statements listed above and agree to observe / undertake these BVDUDC&H-PUNE-IEC requirements while conducting our proposed project / study.

Sign of PI:

Sign of Co-I / P.G. Guide:

Head of Department:

Date:
Department/ Institution Seal: